Remarks/Arguments:

This Amendment is provided to amend the specification, add new dependent claims 4-6, and amend claims 1-3. However, in doing so, no new matter has been added. Upon entry of this Amendment, claims 1-6 will be pending, wherein claims 1-3 are independent.

Objection to the Specification

The Examiner has objected to the abstract of the specification as exceeding 150 words. Accordingly, the Applicants have amended the abstract of the specification to satisfy the word limit, and respectfully request the withdrawal of the objection.

The Examiner has also objected to the specification as failing to provide proper antecedent basis of the claimed subject matter. Specifically, the Examiner has objected to the specification as failing to provide proper antecedent basis of the terms "stanchion", "biasing element", and "interposer". To expedite prosecution, the Applicants have amended the independent claims to revise the terms, and respectfully request the withdrawal of the objection. No new matter or unsupported material has been added, and the amendments are supported elsewhere in the specification (see for example, paragraphs 318-322 and Fig. 39).

The Applicants have also amended the independent claims to delete a pressurization system limitation that is not required for patentability, and have added new dependent claims for this subject matter. The Applicants have also amended the specification to correct a number of typographical errors and informalities.

Objections to the Drawing

The Examiner has objected to the drawings as failing to show exemplary embodiments of a "stanchion", "biasing element", and "interposer". To expedite prosecution, the Applicants have amended the claims to revise the terms, and respectfully request the withdrawal of the objection. No new matter or unsupported material has been added, and the amendments are supported elsewhere in the specification (see again for example, paragraphs 318-322 and Fig. 39).

Rejections of the Claims under 35 U.S.C. 112

The Examiner has rejected claims 1 and 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Examiner asserts that the language used in the claims differs significantly from the language found in the specification, and that one of ordinary skill in the art would not be able to clearly surmise which features of the disclosed invention are being claimed, thereby not fully enabling one of ordinary skill in the art to make and use the invention.

Accordingly, the Applicants have amended claims 1-3 to revise the terms, and respectfully request the withdrawal of the rejection. No new matter or unsupported material has been added, and the amendments are supported elsewhere in the specification (see gain for example, paragraphs 318-322 and Fig. 39).

Rejections of the Claims under 35 U.S.C. 102

The Examiner has rejected claim 1 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,664,654 of Strauss (hereinafter Strauss).

Specifically, the Examiner points to Strauss as disclosing a device for delivering a medicament into the body of a patient by injection into or through the skin of a patient, having a housing with a top surface, a bottom surface adapted to contact the skin of a patient, a needle aperture on the bottom surface, an injection needle adapted for penetration of tissue and for movement through the needle aperture, a reservoir disposed within the housing in fluid communication with the injection needle, a pressurization system for pressurizing the reservoir, a safety member adapted for movement away from the bottom surface and having a covering portion disposed about the needle aperture, and at least one shield protruding from the covering portion, the safety member having a first position wherein the shield of the safety member is initially disposed within the housing and the covering portion is substantially co-planar with the bottom surface of the housing, and a second position wherein the shield of the safety member is partially withdrawn from the housing and the covering portion and shield at least partially cover the needle.

The Examiner further points to Strauss as disclosing such a device further including a spring element disposed to bias the shield of the safety member toward the second position and a movable door having a first position which prevents movement of the safety member, and a second position which allows movement of the safety member, such that the Strauss reference purportedly anticipates the device as recited by the Applicants in claim 1.

As noted above, the Applicants have amended claims 1-3 to revise the terms for clarification and to remove a pressurization system limitation which is not needed for patentability. However, in doing so, no new matter or unsupported material has been added, and the amendments are supported elsewhere in the specification (see again for example, paragraphs 318-322 and Fig. 39).

The Strauss reference describes a safety device for use with a syringe or hypodermic needle (see col. 3, lines 36-39). To do so, the Strauss reference describes the provision of the sliding element 16 which is first manually retracted and then after use, is urged forward by the spring 30 to cover the needle 42. However, the Applicants assert that the system and method described by the Strauss reference does not describe a housing having a bottom surface adapted to contact the skin of a patient, and a needle aperture on the bottom surface. The Examiner points to elements 32 and 34 as describing such. However, the only element of the Strauss reference which can allegedly contact the skin of a patient is the sliding member 16, which is pointed to as describing the safety member.

However, the Applicants recite the safety member as configured for movement away from the bottom surface, and having a covering portion disposed about the needle aperture. In contrast, neither of elements 32 and 34 describe a bottom surface, and where the sliding member 16 allegedly describes a bottom surface, sliding member 16 cannot also describe the safety member as it cannot move away from the bottom surface found upon it.

Still further, the Examiner points to the user grips 24 of the sliding member 16 as describing the at least one shield protruding from the covering portion. As noted above, the Applicants have amended the claims for clarification, and the safety member is now recited having a shield wherein in a first position the shield of the safety member is initially disposed within the housing and the covering portion is substantially co-planar with the

bottom surface of the housing, and in a second position the shield of the safety member is at least partially withdrawn from the housing, and the covering portion and shield at least partially cover the needle. In doing so, the user grips 24 (see for example, Strauss col. 3, line 49 to col. 4, line 2) do not describe a shield as recited by the Applicants.

The Examiner further points to Strauss as disclosing such a device further including a spring element disposed to bias the shield of the safety member toward the second position and a movable door having a first position which prevents movement of the safety member, and a second position which allows movement of the safety member.

Again, as noted above, the Applicants have amended the claims for clarification, and the movable interposer is now recited as a door having a first position which prevents movement of the safety member, and a second position which allows movement of the safety member. In doing so, the catch 18 (see for example, Strauss col. 4, lines 4-8) does not describe a door as recited by the Applicants.

For these reasons, the Applicants assert that the Strauss reference does not disclose or reasonably suggest each element as recited in independent claim 1 as amended, and respectfully request the withdrawal of the rejection under 35 U.S.C. 102(b).

The Examiner has also rejected claim 2 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,186,982 of Gross et al. (hereinafter Gross).

Specifically, the Examiner points to Gross as disclosing a device for delivering a medicament into the body of a patient by injection into or through the skin of a patient, having a housing with a top surface, a bottom surface adapted to contact the skin of a patient, and a needle aperture on the bottom surface, an injection needle adapted for penetration of tissue and for movement through the needle aperture, a reservoir disposed within the housing and in fluid communication with the injection needle, and a pressurization system for pressurizing the reservoir.

The Examiner further points to Gross as disclosing such a device further including a safety member adapted for movement substantially perpendicular to the bottom surface, the safety member having a skin contacting portion disposed about the needle aperture and

substantially covered with adhesive, and at least one shield protruding from the skin contacting portion, the safety member having a first position wherein the shield of the safety member is initially disposed within the housing and the skin contacting portion is substantially co-planar with the bottom surface of the housing, and a second position wherein the shield of the safety member is partially withdrawn from the housing and the safety member at least partially covers the needle, wherein when the device is placed upon the skin of the patient, the skin contacting portion of the safety member is temporarily adhered to the skin and when the device is removed from the skin, the adhesion of the safety member to the skin is sufficient to move the safety member from the first position to the second position, such that the Gross reference purportedly anticipates the device as recited by the Applicants in claim 2.

As noted above, the Applicants have amended claims 1-3 to remove an unnecessary limitation and to revise the terms for clarification. However, in doing so, no new matter or unsupported material has been added, and the amendments are supported elsewhere in the specification (see again for example, paragraphs 318-322 and Fig. 39).

However, in regard to independent claim 2, the Applicants recite an adhesive/skin surface activation feature wherein the adhesion (of the skin contacting portion of the safety member) to the skin surface is sufficient to activate the *perpendicular movement* of the safety member. That is, in an exemplary embodiment of the present invention the safety member is moved *perpendicular to the bottom surface* of the device upon removal.

In contrast, the Gross reference describes a subcutaneous drug delivery device wherein a displaceable cover 52, provided with an adhesive, *rotates* about a hinge toward and from a lower surface of the device 53 to cover a needle 51 (see col. 11, lines 34-50). That is, the Gross reference describes a system and method wherein the displaceable cover is rotated to cover the needle, and does not describe a perpendicular movement as recited by the Applicants.

For these reasons, the Applicants assert that the Gross reference does not disclose or reasonably suggest each element as recited in independent claim 2 as amended, and respectfully request the withdrawal of the rejection under 35 U.S.C. 102(b).

The Examiner has also rejected claim 3 under 35 U.S.C. 102(b) as being anticipated by Gross.

Specifically, the Examiner points to Gross as disclosing a device for delivering a medicament into a body of a patient by injection into or through a skin surface of a patient, having a housing with a top surface, a bottom surface, and a needle aperture on the bottom surface, an injection needle adapted for penetration of the skin surface tissue and for movement through the needle aperture, a reservoir disposed within the housing and in fluid communication with the injection needle, and a pressurization system for pressurizing the reservoir.

The Examiner further points to Gross as disclosing such a device further including a safety member adapted for rotational movement along an arcuate path relative to the bottom surface of the housing, and having a skin contacting portion disposed about the needle aperture and substantially covered with adhesive, and a pivot, such that the safety member has a first position wherein the safety member is substantially co-planar with the bottom surface of the housing, and a second position wherein the safety member is rotated about the pivot and the safety member at least partially covers the injection needle. The Examiner points to Gross as disclosing such a safety member wherein when the device is placed upon the skin surface of the patient, the skin contacting portion of the safety member is temporarily adhered to the skin surface and when the device is removed from the skin surface, the adhesion of the safety member to the skin surface is sufficient to rotate the safety member about the pivot from the first position to the second position, such that the Gross reference purportedly anticipates the device as recited by the Applicants in claim 3.

As noted above, the Applicants have amended claims 1-3 to remove an unnecessary limitation and to revise the terms for clarification. However, in doing so, no new matter or unsupported material has been added, and the amendments are supported elsewhere in the specification (see again for example, paragraphs 318-322 and Fig. 39).

Further, the Applicants have amended independent claim 3 to recite the safety member as having the first position wherein the safety member *is secured* against and substantially co-planar with the bottom surface of the housing, such as in a pre-use position.

This can be achieved through the use of, for example, the door 790 and door latch 791 of Fig. 39. For example, the device of Fig. 39 can be positioned against a skin surface and movement of the push button 780 releases the door latch 791. However, as the device is adhesively positioned against a user's skin, no movement of the door 790 is allowed, but is free to move upon removal of the device (see paragraph 319). In doing so, the Applicants recite a system and method wherein the safety member has the first position wherein the safety member *is secured* against and substantially co-planar with the bottom surface of the housing, such as in a pre-use position.

In contrast, the Gross reference describes a subcutaneous drug delivery device wherein the displaceable cover 52, provided with an adhesive, can rotate about a hinge 54 from a lower surface of the device 53 to cover a needle 51 (see col. 11, lines 34-50). However, the Gross reference describes the system and method wherein the displaceable cover is extended (i.e., rotated from the bottom surface) to cover the needle both prior to and after use. That is, only an application of the device to a skin surface will serve to rotate the cover 52 against the bottom surface of the device as shown in Fig. 5. At all other times, the absence of the skin surface allows the cover 52 to assume the shielding position as shown in Figs. 4 and 6. However, the Applicants assert that none of Figs. 4-6 show the cover 52 *secured* against the bottom surface.

For example, in a pre-use position, the cover 52 is extended, and is prevented from movement against a lower surface of the device by tab 55 (see for example, Fig. 4). Specifically, the tab 55 is provided to prevent the cover 52 from rotating toward the lower surface of the device 53 until removed at use. During use, the skin surface rotates the cover 52 against the bottom surface of the device (see for example, Fig. 5), but there is no provision to secure the cover in this position. After use and removal, the cover 52 is again extended (see for example, Fig. 6). Accordingly, there is no disclosure in the Gross reference of the displaceable cover 52 having any position wherein the cover 52 is *secured* against the *bottom surface* of the device.

For these reasons, the Applicants assert that the Gross reference does not disclose or reasonably suggest each element as recited in independent claim 3 as amended, and respectfully request the withdrawal of the rejection under 35 U.S.C. 102(b).

Conclusion

In view of the above, it is believed that the application is in condition for allowance and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

/Ronald S. Grubb/
Ronald S. Grubb, Reg. #48672
Attorney for Applicant

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Roylance, Abrams, Berdo & Goodman, L.L.P.
1300 19th Street, N.W., Suite 600
Washington, D.C. 20036
T: (202) 659-9076